THAT WHICH IS CLAIMED:

1. A highly concentrated IGF-I composition, said composition comprising biologically active IGF-I or variant thereof in a concentration of at least about 250 mg/ml.

2. The IGF-I composition of claim 1, wherein said composition is a low salt-containing syrup.

3. The IGF-I composition of claim 2, wherein said syrup comprises IGF-I in a concentration of about 250 mg/ml to about 500 mg/ml.

4. The IGF-I composition of claim 2, wherein said syrup comprises IGF-I in a concentration of about 350 mg/ml, and wherein said syrup has a density of about 1.07 g/ml and a viscosity of about 15,700 cps.

5. A method for preparing a highly concentrated form of biologically active IGF-I or variant thereof, said method comprising:

a) preparing a solution comprising said IGF-I or variant thereof, wherein said solution has an initial pH less than or equal to about pH 5.0;

b) adjusting said solution pH to a final pH equal to or greater than about pH 5.5, wherein said adjustment results in precipitation of said IGF-I or variant thereof to form a syrup comprising said IGF-I or variant thereof in a concentration of at least about 250 mg/ml; and

c) separating said syrup from said solution.

6. The method of claim 5, wherein said syrup is a low salt-containing syrup comprising IGF-I in a concentration of about 250 mg/ml to about 500 mg/ml.

7. The method of claim 5, wherein said syrup is a low salt-containing syrup comprising IGF-I in a concentration of about 350 mg/ml, and wherein said syrup has a density of about 1.07 g/ml and a viscosity of about 15,700 cps.

8. A highly concentrated form of biologically active IGF-I prepared according to the method of claim 5.

9. A method for preparing a highly concentrated form of biologically active IGF-I or variant thereof, said method comprising:

a) preparing a high concentration solution of IGF-I or variant thereof in the presence of a solubility enhancer;

b) removing said enhancer from solution, wherein said removal of said enhancer results in precipitation of said IGF-I or variant thereof to form a syrup comprising said IGF-I or variant thereof in a concentration of at least about 250 mg/ml; and

c) separating said syrup from said solution.

10. The method of claim 9, wherein said solubility enhancer is arginine or an arginine analogue.

11. The method of claim 9, wherein said solubility enhancer is guanidine hydrochloride.

12. A highly concentrated form of biologically active IGF-I prepared according to the method of claim 9.

13. A kit for reconstituting a pharmaceutical composition comprising biologically active IGF-I or variant thereof, said kit comprising a carrier being compartmentalized to receive in close confinement therein one or more container means, wherein one of said container means contains a highly concentrated form of biologically active IGF-I or variant thereof, wherein said IGF-I or variant thereof is present in a

concentration of at least about 250 mg/ml, and another of said container means contains a pharmaceutically acceptable buffered solution having a pH less than or equal to about pH 5.0.

14. A method of preparing a composition comprising biologically active IGF-I, said method comprising:

a) preparing a highly concentrated form of biologically active IGF-I or variant thereof, wherein said IGF-I or variant thereof is present in a concentration of at least about 250 mg/ml; and

b) incorporating said highly concentrated form of biologically active IGF-I or variant thereof into at least one substance to form said composition.

15. The method of claim 14, wherein said highly concentrated form of biologically active IGF-I or variant thereof is a low salt-containing syrup comprising IGF-I in a concentration of about 250 mg/ml to about 500 mg/ml.

16. A composition prepared according to the method of claim 15, wherein said composition is a pharmaceutical composition.

~~17.~~ The pharmaceutical composition of claim ~~16~~, wherein said composition is a sustained-release formulation.

~~18.~~ The pharmaceutical composition of claim ~~16~~, wherein said composition is a gel formulation.

19. A composition prepared according to the method of claim 15, wherein said composition is a cryogenically produced PLGA microsphere.

20. The microsphere of claim 19, wherein said microsphere comprises a lyophylized form of said syrup.

21. A method of therapy for an IGF-I responsive condition in a mammal, wherein said method comprises administering to said mammal a pharmaceutical composition comprising a highly concentrated form of biologically active IGF-I or variant thereof, wherein said IGF-I or variant thereof is present in a concentration of at least about 250 mg/ml.

22. The method of claim 21, wherein said highly concentrated form of biologically active IGF-I or variant thereof is a low salt-containing syrup comprising IGF-I in a concentration of about 250 mg/ml to about 500 mg/ml.

23. The method of claim 21, wherein said pharmaceutical composition is administered as a sustained-release formulation.

24. The method of claim 21, wherein said pharmaceutical composition is administered as a gel formulation.

25. The method of claim 21, wherein said pharmaceutical composition is administered as an implant.

26. The method of claim 21, wherein said pharmaceutical composition is administered in a miniature pump for prolonged delivery at a therapeutic site undergoing therapy for said IGF-I-responsive condition.

27. The method of claim 26, wherein said pump is osmotically driven.

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